

1631

**AMENDMENT TRANSMITTAL LETTER (Small Entity)**

Applicant(s): Pospisilik et al.

Docket No.

20488/25-CIP

Serial No.  
09/932,546

Filing Date  
August 17, 2001

Examiner  
Morin, Michael L.

Group Art Unit  
1631

Invention: **USE OF DIPEPTIDYL PEPTIDASE IV ENZYME INHIBITORS FOR LOWERING BLOOD PRESSURE IN MAMMALS**

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

- ☒ Small Entity status of this application has been established under 37 CFR 1.27 by a verified statement previously submitted.
- ☐ A verified statement to establish Small Entity status under 37 FR 1.27 is enclosed.

The fee has been calculated and is transmitted as shown below.

**CLAIMS AS AMENDED**

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST # PREV. PAID FOR	NUMBER EXTRA CLAIMS PRESENT	RATE	ADDITIONAL FEE
TOTAL CLAIMS	3 -	20 =	0 x	\$9.00	\$0.00
INDEP. CLAIMS	1 -	3 =	0 x	\$43.00	\$0.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT					\$0.00

- ☒ No additional fee is required for amendment.
- ☐ Please charge Deposit Account No. \_\_\_\_\_ in the amount of \_\_\_\_\_
- ☐ A check in the amount of \_\_\_\_\_ to cover the filing fee is enclosed.
- ☒ The Director is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0369
- ☒ Any additional filing fees required under 37 C.F.R. 1.16.
- ☐ Any patent application processing fees under 37 CFR 1.17.

Dated: **October 27, 2003**

*Signature*

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I certify that this document and fee is being deposited on Oct. 27, 2003 with the U.S. Postal Service as first class mail under 37 C.F.R. 1.8 and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

*Sandra Witttrup*

*Signature of Person Mailing Correspondence*

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*Typed or Printed Name of Person Mailing Correspondence*

cc: Customer No.: 21710



Attorney Docket No. 20488/25-CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Pospisilik et al.

Art Unit: 1631

U.S.S.N.: 09/932,546

Confirmation No.: 4799

FILED: August 17, 2001

Examiner: Borin, Michael L.

FOR: *USE OF DIPEPTIDYL PEPTIDASE IV EFFECTORS FOR LOWERING  
BLOOD PRESSURE IN MAMMALS*

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By:

*Sandra J. Wittrup*  
Sandra J. Wittrup

October 27, 2003

Date

MAIL STOP NON-FEE AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

This is being filed in response to the Office Action mailed from the U. S. Patent and Trademark Office on September 26, 2003 in the above-identified application and for which a response is due on October 27, 2003. This response is believed to be timely filed. If, however, a petition for extension is required please consider this paper such a petition. Authorization is hereby given to charge Deposit Account No. 50-0369 in connection with any fees for extension of time that are necessary to permit entry of this response.

**In the claims:**

Please cancel claims 2-6 and 9-10 without prejudice and amend claims 1 and 8 as follows:

1. (CURRENTLY AMENDED) A method for lowering blood pressure levels and post-prandial hyperglycemia in mammals comprising administering a therapeutically effective amount of at least one inhibitor of Dipeptidyl Peptidase (DP IV) or enzymes having DP IV-like enzyme activity.
2. (CANCELLED) The method according to claim 1, wherein said at least one inhibitor is selected from the group consisting of alanyl pyrrolidine, isoleucyl thiazolidine, and N-valyl prolyl, O-benzoyl hydroxylamine.
3. (CANCELLED) The method according to claim 1, wherein said at least one inhibitor is administered orally in combination with at least one carrier substance.
4. (CANCELLED) The method according to claim 1, wherein said at least one inhibitor is administered in multiple administrations.
5. (CANCELLED) The method according to claim 1, wherein said amount of the inhibitor compound is between 0.1 mg to 10.0 mg per kilogram of body weight.
6. (CANCELLED) The method according to claim 1, wherein the mammals demonstrate clinically inappropriate basal and post-prandial hyperglycemia or blood pressure levels or both.
7. (ORIGINAL) The method according to claim 1, wherein the administration is for the prevention or alleviation of pathological abnormalities of metabolism of mammals such as glucosuria, hyperlipidaemia, metabolic acidosis and *Diabetes mellitus* and results in lowered blood pressure.

8. (CURRENTLY AMENDED)     The method of claim 1 A method for lowering blood pressure levels in mammals experiencing blood pressures in excess of 150 mm Hg comprising the periodic administration of a therapeutically effective amount of an inhibitor of DP-IV enzyme activity.
9. (CANCELLED)     The method of claim 8 wherein said inhibitor comprises isoleucyl thiazolidine.
10. (CANCELLED)     A method for lowering blood pressure levels associated with elevated blood glucose levels in mammals comprising the oral administration of a therapeutically effective amount of an inhibitor of DP-IV enzyme activity selected from the group consisting of alanyl pyrrolidine and isoleucyl thiazolidine.

## **REMARKS**

### **I. Status of the claims**

Claims 1-10 are pending. By the present amendment claims 2-6 and 9-10 have been cancelled without prejudice.

### **II. Amendment to the claims.**

No new matter has been added as a result of the above-presented amendments. The amendments to claims 1 and 8 further emphasize Applicants' invention and find full support within the specification. In particular, amendments to claims 1 and 8 find support throughout the specification, examples, figures, tables and originally filed claims with particular reference to page 7 lines 7 to 11.

Applicants respectfully request expeditious consideration and allowance of the present application. The Examiner is invited and encouraged to telephone the undersigned if he believes such would facilitate furtherance of the prosecution of the present application.

### **III. Reasons for Cancellation of Claims.**

Applicants respectfully submit that the above cancellation of claims is made merely to facilitate its present commercial interest and not for reasons of prior art. Applicants respectfully reserve the right to present such claims in subsequent applications.

### **IV. Election of Species.**

In paragraph 2, the Examiner stated that pending claims 1-10 are individually or dependently directed to a plurality of disclosed patentably distinct species of inhibitors, as well as plurality of conditions to be treated. The Examiner requested that Applicants elect a single disclosed species of each for the following: one of the inhibitors listed in claim 2 and a particular instance of elevated blood pressure, such as those recited in claims 8 and 10. The Examiner is requesting that the Applicants elect a single disclosed species. Applicants respectfully submit that this election of species requirement is moot due to the cancellation of claims 2-6 and 9-10.

Applicants respectfully submit that the cancellation of claims as noted above results in remaining claims having no various species of the invention. Specifically, Applicants respectfully submit that by its cancellation of claims 2-6 and 9-10 that there will not be a serious burden on the Examiner if election of species is not required because regardless of the claims prosecuted, the field of search for the remaining generic claims is identical to the other. A separate field of search is shown to exist only when one of the distinct subjects can be searched in places where no pertinent art to the other subject exists. In this case, however, there is no indication that a separate field of search is required for each of the remaining generic claims. Thus, Applicants respectfully contend that there will not be a serious burden on the Examiner and would therefore respectfully request that the species election be withdrawn.

### CONCLUSION

The claims remaining within the application are believed to patentably distinguish over the prior art and to be in condition for allowance. Early and favorable consideration of this application is respectfully requested.

Respectfully submitted,




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